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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. CONFIRMATION NO.
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09/509,377

08/28/2000

Sergey Matasov

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United States Patent and Trademark Office Commissioner for Patents Art Unit 3739 Examiner Mr. Leubecker, John P. P.O. Box 1450, Alexandria VA 22313-1450 United States of America EXAMINER
LEUBECKER, JOHN P
ART UNIT PAPER NUMBER

3739

OFFICIAL

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SEP 0 3 2003

DATE MAILED: September 3, 2003

Please, find attached the reply on the Office Action of June 9, 2003 concerning this application.

#### Enclosed:

Copy and certified English translation of the Official Bulletin
of the State Committee of Inventions and Discoveries at the
USSR SCST No. 42 from November 15, 1989

4 sheets

2. Corrected drawing 4/4

3 copies

3. Substitute specification and claims of the application 09/509,377:

amended page 3amended page 9

I sheet I sheet

4. Statement of amendments

2 sheets

5. Remarks/Arguments

1 sheet

6. Version with markings to show changes made

2 sheets

Faithfully Yours,

Sergev Matasov, M.D.

Received from < > at 9/3/03 1:32:23 PM [Eastern Daylight Time]

Page 2

#### Acc rding to item 1.

Thank You for the advice. I have consulted the US registered patent attorney and the European patent attorney. They affirm, that the main problem is in the infringement of 35 U.S.C. 102 (b) at granting of US Patent 6,485,409 (Voloshin et al.).

#### According to item 2.

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003:
Status of the SU Inventor's Certificate No.1522466.	" Applicant's inventor's certificate, which was published on July 15, 1989, is prior art with respect to this application ".	<ul> <li>The statement of Examiner about publication of SU Inventors Certificate No. 1522466 on July 15, 1989 does not square with reality.</li> <li>In reality: <ul> <li>On February 13, 2003 Examiner received the certificated copy and the English translation of SU Inventors Certificate No. 1522466, which has a stamp "For office use only".</li> </ul> </li> <li>In the Official Bulletin of the State Committee of Inventions and Discoveries at the USSR State Committee of Science and Engineering No. 42 from November 15, 1989 is said, that the inventors certificates from No. 1522442 till No. 1523037 are not to be published (see Enclosure No.1).</li> </ul>
		• The SU Inventors Certificate No. 1522466 was published after October 3, 1997 (see PCT Gazette 15/1999 from April 15, 1999, publication WO99/17655) and therefore is not prior art, but the component part of this application.

## According to item 3.

Thank You for the approval of proposed drawing. Corrected drawing is enclosed (see Enclosure No.2)

## According to item 4 (a).

Thank You for the observation. The dot is applied. The newly added sentences on page 3 are amended (see Enclosure No. 3).

Page 3

## According to items 4 (a) and (b). (Repeatedly, for the first time in my letter from February 13, 2003).

Application/Control Number: 09/509,377

Art Unit: 3739

Page 4

	liquidate its gap (25) with the endoscopic tube (3).
	<ul> <li>The real subject matter of claims 3 and 8 was fully and clearly described in the application at the time it was filed. Please not the application PCT/LV98/00006:</li> </ul>
	• page 3 lines 18-19 and 23-26;
·	• page 5 lines 7-9;
	• page 7 lines 38-40;
	• page 9 lines 11-13;
	• page 10 lines 1-3;
	• Fig. 1 c, 1 c, 1f,
	Abstract, lines 2, 3.

Herewith I propose the correction of lines 15-19 on page 3, where the mentioning of pressure is excluded: The stability of diameters depends on the compactness of the cylinder. In one of the embodiments the definite compactness of cylinder ensures the gap with endoscopic tube during their joining and in the process of invagination, in the other - only during the joining. There are possible also the interim variants of embodiments.

#### According to item 5.

Concerning claim 1. The amended claim looks like as follows:

1. An endoscope, comprising an invaginator which is a thin-walled tube, compactly placed on the distal part of an endoscopic tube in the shape of small layers and/or pleats.

Concerning claim 2. The amended claim looks like as follows:

2. The endoscope according to claim 1, wherein said invaginator is formed in the shape of a compact hollow cylinder, which has a gap with the distal part of the endoscopic tube.

Concerning claims 3, 5, 7, 8, 10, 16 and 17. Thank You for the proposals. They are accepted.

According to item 7. (Repeatedly, for the first time in my letter from February 13, 2003).

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003;
Claims 3 and 8 and description of their subject matter in the specification.	"Claims contains subject matter which was not described in the	The statements of Examiner "the working pressure keeps the gap 25" and "the working pressure applied to gap 25" do not square with reality.  In reality:
	specification in	Examin r has at first distorted ("the working pressure keeps

Application/Control Number: 09/509,377

such a way ...

Art Unit: 3739

the gap 25", "the working pressure applied to gap 25") the subject matter of claim 3 (8), and then begin to allege, that this (distorted) subject matter was not described in the specification in comply with the 35 U.S.C. 112, first paragraph. In my application there is no and could not be the description of subject matter, distorted by Examiner. • The working pressure, which exerts influence upon all the elements limiting its cavity, presses the uneverted part of invaginator to the endoscopic tube. This problem is typical for all the endoscopes, comprising an invaginator (see page 1, lines 12-15, 38-41 of the application PCT/LV98/00006). • US Patent 5,259,364 (Bob et al.) declares the solving of this problem by means of pressure, which is forced not only into the chamber (42) of the everted part (26) of invaginator, but also into the gap space (44) between the invaginator (32) and endoscopic tube (2). • In my application the working pressure into the cavity (25) is not feeded. It is inadmissible. The gap (25) is kept by the invaginator formed in a hollow cylinder (23), which has a definite compactness. The working pressure in cavity (14) is not able to grasp the compact cylinder (23), in other words - to liquidate its gap (25) with the endoscopic tube (3). In my application the real subject matter of claims 3 and 8 was fully and clearly described in the application at the time it was filed. Please note the application PCT/LV98/00006: page 3 lines 18-19 and 23-26; page 5 lines 7-9;

• Abstract, lines 2, 3.

page 7 lines 38-40; page 9 lines 11-13; page 10 lines 1-3; Fig. 1 c, 1 e, 1f; Application/Control Number: 09/509,377

Art Unit- 3739

Herewith I propose the correction of lines 15-19 on page 3, where the mentioning of pressure is excluded: The stability of diameters depends on the compactness of the cylinder. In one of the embodiments the definite compactness of cylinder ensures the gap with endoscopic tube during their joining and in the process of invagination, in the other - only during the joining. There are possible also the interim variants of embodiments.

## According to item 9. Thank You for the observations. They are accepted.

Concerning claim 3. The amended claim looks like as follows:

The endoscope according to claim 2, wherein said cylinder has a compactness, which ensures said gap in the process of invagination of the endoscopic tube.

## Concerning claim 8. The amended claim looks like as follows:

8. The endoscope according to claim 7, wherein said cylinder has a compactness, which ensures said gap in the process of invagination of the endoscopic tube.

#### Concerning claim 13. The amended claim looks like as follows:

13. The endoscope according to claim 12, wherein a cavity of said tip communicates with a cavity of intestines.

Concerning claim 15. The claim 15 is withdrawn.

Concerning claim 16. Thank You for the observation. The amended claim looks like as follows:

The endoscope according to any of claims 1, 2, 3, 7, 8, wherein the endoscopic tube further comprises a distal drives of traction lines, bending its distal end, which are cylinder-piston units, connected to the pressure of gas or liquid.

Concerning claim 17. The claim 17 is withdrawn.

Concerning claim 18. The subject matters of this claim are following:

- 1. the biopsy forceps, which are the flexible hermetic tube,
- 2. the piston of biopsy channel, which is placed on the distal end of the flexible hermetic tube.

These subject matters are illustrated on Fig. 4d under the numbers 63-68 and described in the specification on:

- page 4, lines 13-16;
- page 5, lines 28-30;
- page 6, lines 38-43;
- page 8, lines 17-22.

Concerning claim 19. Thank you for the observation. The amended claim looks like as follows:

The endoscope according to claim 16, further comprising a distal drive of traction line of a cutters of said biopsy forceps.

Page 7

### According to item 11.

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003:
The status of SU Inventors Certificate No.1522466.	"Claims 1, 2, 4- 7, 9-12, 14 and 20 are rejected under 35 USC	The statement about publication of SU Inventors Certificate No. 1522466 on July 15, 1989 does not square with reality.  In reality:
	102 (b) as being anticipated by Matasov"	<ul> <li>On February 13, 2003 Examiner received the certificated copy and the English translation of SU Inventors Certificate No. 1522466, which has a stamp "For office use only".</li> </ul>
		• In the Official Bulletin of the State Committee of Inventions and Discoveries at the USSR State Committee of Science and Engineering No. 42 from November 15, 1989 is said that the inventors certificates from No. 1522442 till No. 1523037 are not to be published (see Enclosure No.1).
		• The SU Inventors Certificate No. 1522466 was published after October 3, 1997 (see PCT Gazette 15/1999 from April 15, 1999, publication WO99/17655) and therefore is not prior art, but the component part of this application.
		• Examiner has greatly distorted the contents of the SU Inventors Certificate No. 1522466, but its status (as the component part of my application) excludes the necessity of discussion.

According to item 12. (Repeatedly, for the first time in my letter from February 13, 2003).

Examiner has rejected the claims 1-9, 11, 12 and 20 under 35 USC § 102 (b), as being anticipated by Bob et al. (U.S. Pat. 5,259,364).

Herewith I repeatedly adduce the proofs, that the subject matters of claims 1-9, 11, 12 and 20 (from February 13, 2003) of my application have not any common features with U.S. Pat. 5,259,364 (Bob et al.).

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003;
Examiner's	" As shown on	The statement of Examiner, that the invaginator according to US
statement, that	Figure 2. the	Patent 5,259,364 (Bob et al.) "would be gathered on the distal

Page	8
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the invaginator	invaginator (24)	end" d not square with reality.
according the	would be	
US Patent	gathered on the	In reality:
5,259,364	distal end (as	<ul> <li>About the location of the "distal end" of endoscope one should</li> </ul>
"would be	the endoscope	judge by its objective.
gathered on the	tube enters the	
distal end".	anus 30) by	• In the US Patent 5,259,364 on the Figure 2, mentioned by
	pleats (52)	Examiner, there is no "distal end" of endoscope.
	(col.5, lines	
·	7-9)"	• In the US Patent 5,259,364 on the Figure 2 are shown:
		<ul> <li>The distal part of the endoscopic tube (2). There are no any "pleats 52" on it.</li> </ul>
		• The proximal part of the endoscopic tube (2) with "pleats (52)".
		• In the US Patent 5,259,364 on the Figure 1 are shown:
·		• the "distal end" of the endoscopic tube (2), that is the
		head piece (38), which includes the objective,
		<ul> <li>the distal part of the endoscopic tube (2), that is the section above the break,</li> </ul>
		• the proximal part of the endoscopic tube (2), that is the
		section below the break.
		• In the US Patent 5,259,364 on the Figure 1 there is no "pleats (52)":
	į	<ul> <li>on the "distal end", mentioned by Examiner,</li> </ul>
		• on the distal part of the endoscopic tube (2),
		<ul> <li>on the proximal part of the endoscopic tube (2).</li> </ul>
·		• In the US Patent 5,259,364 in column 5, lines 7-9 there is no the statement of Examiner, that "the invaginator would be gathered on the distal end".
		In the US Patent 5,259,364 in column 5, lines 9-11 is said: "The rearward, in FIG.2 lower end of the supply portion 52 is attached to the rear wall of pressure chamber 50". Thus, the supply or storage portion (52) of the invaginator is always located in the chamber (50), i. on the proximal part of the endoscopi tube (2).

Page 9

		<ul> <li>In my application, in contrast to the US Patent 5,259,364, the uneverted end (7) of the cylinder of invaginator (23) is joined with the seal (29) on the distal part of the endoscopic tube (3). That is why the 1,5-meters long store of invaginator (23) is always located on the distal part of the endoscopic tube (3) and is moving together with it.</li> </ul>
Examiner's statement, that the invaginator according the US Patent 5,259,364	"As to claims 2, 3 and 8, pleats (52) form a compact hollow cylinder which defines a gap	The statement of Examiner, that in US Patent 5,259,364 (Bob et al.) "pleats (52) form a compact hollow cylinder which defines a gap" do not square with reality.  In reality:  In US Patent 5,259,364 (see Figure 2) invaginator under the
"defines a gap",	(note space between pleats and endoscope tube in Figure	number (52) is represented by the wavy lines. The bollow cylinders are usually represented by straight lines.  • In US Patent 5,259,364 there are no words "cylinder",
	2) that is maintained under working pressure (col. 5,	"compact", word-combinations "compact cylinder" "compact hollow cylinder" or their synonyms.
	lines 18-22)."	• In US Patent 5,259,364 on Figure 2 there is represented the portion (68) of the pressure chamber (50), limited by the invaginator (52) and the endoscopic tube (2). The presence of a gap between them is ensured not by the compactness of the portion (52), but by the pressure which is feeding in the portion (68) of pressure chamber (50). This pressure must be equal to the pressure in the portion (62) of pressure chamber (50).
		• In US Patent 5,259,364 in case of prevalence of pressure in the portion (62) of pressure chamber (50) over the pressure in the portion (68) of pressure chamber (50), the supply portion (52) of invaginator will adhere to the endoscopic tube (2).
		• In US Patent 5,259,364 in case of prevalence of pressure in the portion (68) of pressure chamber (50) over the pressure in the portion (62) of pressure chamber (50), the gap between the

Page 10

Г		supply portion (52) of invaginator and the endoscopic tube (2)
		will appear, but invaginator (24) will adhere to the outer
		portion (26).
		·
		• In US Patent 5,259,364 in the indicated col. 5, lines 18-22
,		there is no the statement of Examiner - there is said that the
		pressurized fluid can be supplied into the portion (68) of the pressure chamber (50).
		pressure chamber (50).
		• In US Patent 5,259,364 the working pressure arrives into the
		portion (68), then into the gap space (44) and then inevitably
		gets into the intestne (14). The value of working pressure is
		0,35 bar. The obvious threat of intestines ruptures by this
		pressure excludes its use outside the closed cavity.
		In my application for formation of compact hollow cylinder
		(23) from a thin-wall tube the press-mold and high
		temperature are used (see my letter from February 13, 2003).
		Formation of the gap (25) is ensured by the die, which
		diameter exceedes the diameter of the distal part of endoscopic
		tube (3). By the compactness the hollow cylinder (23)
		resembles the cigar.
Formulating of	"As to claim 4,	• In US Patent 5,259,364 the camera chip is installed into the
claim 4.	the distal end (38) of the	head piece (38).
	(38) of the endoscope tube	In my application claim 4 declares the movable seal (29)
	encloses a	between the endoscopic tube (3) and the movable uneverted
	camera and is	end (7) of the invaginator (23).
	thus inherently	
	sealed."	I thank You for the constructive observation and propose the
		amended claim 4:
		4. The endoscope according to any of claims 1 to 3, further comprising a seal between the endoscopic tube and the
		uneverted end of said invaginator.

	As to claim 5, ote shell (50)."	In my application, due to the int mal transverse pleats (48) of the external cover of endoscopic tube (3), as well as due to the widenings and narrowings (24) of the diameters of cylinder (23), the distal part of endoscope becomes extremely flexible.
		In my application the conducting of endoscope with extremely flexible distal part along the rectum (which has a form of ampoule with diameter till 8 cm) into the sigmoid intestine is ensured by the shell (22) (see Fig. 1b, 1c; page 5 lines 38-39).
		<ul> <li>In my application the shell (22) serves as a sheath-conductor of invaginator (23) and of the distal part of endoscopic tube (3) along the rectum.</li> </ul>
		<ul> <li>In US Patent 5,259,364 there is no neither constructional, nor functional analogue of the shell (22). The object (50) is an out-organ container for the placing of:</li> <li>means (70),</li> <li>roller pairs (72),</li> <li>annular seal (58),</li> <li>supply portion (52) of invaginator.</li> </ul>
,		• In US Patent 5,259,364 the pressure chamber (50) is not intended for the insertion into rectum.
·		I propose the amended claim 5:  5. The endoscope according to any of claims 1 to 3, further comprising a shell of said invaginator, commensurate to the diameter of said invaginator and to the length of rectum.
The main point	"As to claims 6	The preservative is the removable object by its definition.
of the term preservative in claim 6 and part of claim 7.	and 7, endoscopic tube (2) inherently comprises an outer protective	• In my application claims 6 and 7 declares the separate from the endoscopic tube (3) subject matter - the distal preservative (26) (see Figure 1c, 1f, page 7 line 23; page 3 lines 23-25).

Page 12

Application/Control Number: 09/509,377 Art Unit: 3739

	sheath which meets the limitation of a preservative."	•	In my application removable preservative (26) isolates the "outer protective sheath" of the endoscopic tube (3), which one was opposed by Examiner to the preservative (26).  In my application the preservative (26) "protect the patient from infections seated in endoscopic tube 3, but tube 3 - from getting contagious during endoscopy." (page 6, lines 27-29). Preservative (26), in combination with others elements, allows repeatedly use the endoscopic tube (3) without disinfection.
·		•	In US Patent 5,259,364 there is no preservative of the distal part of endoscopic tube (2).
Novelty of claim 9.	"As to claim 9, note seal (58)."	•	In US Patent 5,259,364 the seal (58) pressurizes the cavity of uneverted part of invaginator.
		•	In my application seal (13) pressurizes the cavity of everted part of invaginator.
The main point of the term tip and novelty of	"As to claim 11, note tip (38)."	•	The tip, as well as the preservative, is removable object by its definition, for example, the tip of fountain-pen.
claim 11.		•	In US Patent 5,259,364 the head piece (38) inheres in the tube (2) as a head in a body.
		•	In my application is claimed the tip (6), which, following the preceding analogue, is the "hat" of the head of endoscopic tube (3).
		•	In my application the ability to remove the tip (6) is confirmed by its belonging to the disposable cartridge (see Figures 1c, 1f; page 3, lines 24-25, page 5 lines 8-10).
The main point	"As to claim 12,	•	The tip, comprising the glass, is removable object by its
of the term tip	a protective		definition.
and novelty of	glass is inherent	•	In US Patent 5,259,364 there is no tip of endoscopic tube (2).
claim 12.	since a camera	•	In US Patent 5,259,364 the head piece (38) is not removable.
	for viewing is	•	In my application in claim 11 is claimed the removable tip (6)
	located in the		of the endoscopic tube (3).
	tip (38)."	•	In my application in claim 12 is claimed the removable tip (6) according to claim 11 with the protective glass (33).

		The removable tip (6) with glass (33) according to claim 12 is illustrated on Figure 1f and described on page 3, lines 27-28; page
	6, line 38; page 7, line 30).	
		At the same time, taking into account the plurality of variants of interpretations of the term tip, herewith I propose the amended claim 11:  11. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a removable tip of the endoscopic tube.
Formulating of claim 20.	"As to claim 20, the invaginator (24) is cylindrical (i.e. shape of a cylinder/piston unit)."	<ul> <li>There is known very many cylindrical objects. Under the cylinder-piston unit is known the concrete construction, which include two inherent elements - cylinder and its hermetic piston. The pressure, which is feeding into cylinder, realizes the job of lineal displacement of piston or cylinder.</li> <li>In the US Patent 5,259,364 on Fig 1 and 2 the cylindrical invaginator (24) has no piston.</li> <li>In the US Patent 5,259,364 is not said, that the cylindrical invaginator (24) is the part of cylinder-piston unit.</li> <li>I thank You for the constructive opposition, the amended claim looks like as follows:</li> <li>An endoscope comprising a mechanism for introduction of an endoscopic tube, which is a cylinder-piston unit, connected to the pressure of gas or liquid.</li> </ul>

## According to item 14.

Subject of discussion:	Examiner on June 9, 2003;	Applicant on September 3, 2003:
Novelty of claim 16.	"Claim 16 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Matasov (SU 1522466) in view of Wilk et	<ul> <li>The SU Inventors Certificate No. 1522466 was published after October 3, 1997 (see PCT Gazette 15/1999 from April 15, 1999, publication WO99/17655) and therefore is not prior art, but the component part of my application.</li> <li>Thus, SU Inventors Certificate No. 1522466 in view of U.S., Pat. 5,396,879 can not discredit the novelty of my invention.</li> </ul>

Page 14

al. (U.S. Pat. 5,396,879)	·
3,390,879)	
and further as	• In my application for bending of distal end of the endoscopic
being	tube (3), which repeats the colon curves, there are described
unpatentable	the distal drives of traction lines in the shape of classical
over Bob et al.	cylinder-piston unit (claim 16).
In view of Wilk	
et al."	Under the cylinder-piston unit is known the classic construction,
	which includes two inherent elements - cylinder and its hermetic
	piston. The pressure of fluid, which is feeding into cylinder,
	realizes the job of lineal displacement of piston or cylinder.
	• In the U.S.Pat. 5,396,879 is described the distal drive on the
·	base of solenoid, whose tiny force could not ensure the
	bending of distal end of endoscopic tube (3), which repeats
	the colon curves.
	• U.S.Pat. 5,259,364 in view of U.S.Pat. 5,396,879 could not
	serve as the prior art, because not one from these patents do not
	include not one of the subject matters of claims of my
·	application.
·	I thank You for the observation, the amended claim looks like as follows:
·	The endoscope according to any of claims 1, 2, 3, 7, 8,
	wherein the endoscopic tube further comprises a distal
	drives of a traction lines, bending its distal end, which are
	cylinder-piston units, connected to the pressure of gas or
	liquid.

## According to item 15.

The claim 17 is withdrawn from Claims.

## According to item 16.

Examiner asserts, that "Applicant relies heavily on disclosed subject matter".

In this connection I kindly ask to draw the attention, that all three Examiner's statements, concerning the claims 1, 2 and 3, do not square with reality. They are as follows:

1. Statement, that the invaginator according to US Patent 5,259,364 (Bob et al.) "would be gathered on the distal end" of endoscopic tube.

Page 15

- 2. Statement, that in US Patent 5,259,364 "pleats (52) form a compact hollow cylinder which defines a gap".
- Statements, that in my application "the working pressure keeps the gap 25" and "the working pressure applied to gap 25".

The persevering reiteration of these three statements, as well as raising of the fourth unfounded statement – about the publication of SU Inventor's Certificate № 1522466 on July 15, 1989 – I am crediting with the infringement by Examiner of 35 U.S.C. 102 and with illegal grant of US Patent 6,485,409 (Voloshin et al.)

In connection with grant of US Patent 6,485,409, please, note that:

- US Patent 6,485,409 (claims 4, 5, 10) comprises invaginator, gathered on the distal part of endoscope.
- More than one year prior the date of patent application 09/646,941, according which the US Patent 6,485,409 was granted, there was printed publication WO 99/17655 of my application, which describes the endoscope with invaginator on its distal part (see PCT/LV98/00006 page 1 lines 12-14, 18-21, 31-35; page 3 lines 3-4, 17-19, 27-29; page 5, lines 7-9; page 7 lines 38-40; page 9 lines 11-13; page 10, lines 1-3; Fig. 1c, 1c, 1f).
- In accordance with 35 U.S.C. 102 my patent application 09/509,377 comprises the SU Inventor's Certificate No. 1522466 with priority from August 27, 1978, wherein is firstly described the colonoscope with invaginator, gathered on the distal part of endoscopic tube.
- Examiner at the same time has examined the patent application 09/646,941 and my application 09/509,377, as well as made the International Search according the International application No. PCT/IL00/00017, which one had a continuation in the patent application 09/646,941.
- In the course of International search of International application No. PCT/IL00/00017 Examiner opposed to it the US Patent 5,259,364 (Bob et al.), but on November 26, 2002 granted the US Patent 6,485,409. In the US Patent 6,485,409 the US Patent 5,259,364 is mentioned as a cited reference.